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No. 04-623

In the Supreme Court of the United States

Alberto R. Gonzales, Attorney General, *et al.*,
Petitioners

v.

State of Oregon *et al.*,
Respondents

On Writ of Certiorari to the
United States Court of Appeals
for the Ninth Circuit

BRIEF FOR THE RESPONDENTS
filed by Peter A. Rasmussen, M.D.
and David M. Hochhalter

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QUESTION PRESENTED

Whether the Attorney General has permissibly construed the Controlled Substances Act, 21 U.S.C. 801 *et seq.*, and its implementing regulations to prohibit the distribution of federally controlled substances for the purpose of facilitating an individual's suicide, regardless of a state law purporting to authorize such distribution.

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STATEMENT OF THE CASE[1]

One day after the State of Oregon filed suit, practitioner-respondents Peter A. Rasmussen, M.D., and David M. Hochhalter, a physician and a pharmacist, ("practitioners") filed a complaint in intervention suing United States Attorney General John Ashcroft, *et al.*, to prevent criminal and civil enforcement proceedings against them for having prescribed and dispensed schedule II controlled substances under the Oregon Death With Dignity Act, Or. Rev. Stat. 127.800 *et seq*.

The proceedings below

On November 8, 2001, the district court granted all respondents' request for a temporary restraining order, enjoining the Attorney General from enforcing the Controlled Substances Act (CSA) against Oregon physicians and pharmacists practicing in accord with the Oregon Death With Dignity Act.

On November 20, 2001, at the conclusion of the preliminary injunction hearing, the parties agreed to extend the temporary restraining order in lieu of a court ruling on respondents' motion for a preliminary injunction.

On April 17, 2002, the district court granted summary judgment in favor of all respondents and permanently enjoined the Attorney General from enforcing, applying, or otherwise giving any legal effect to his enforcement directive. See Pet. App. 97a. The district court reasoned as follows:

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[1] In accord with Supreme Court Rule 24(2), practitioner-respondents supplement petitioners' statement.

> I conclude that Congress did not intend the CSA to override a state's decisions concerning what constitutes legitimate medical practice, at least in the absence of an express federal law prohibiting that practice. Similarly, I conclude that Congress never intended, through the CSA or through any other current federal law, to grant blanket authority to the Attorney General or the DEA to define, as a matter of federal policy, what constitutes the legitimate practice of medicine.

Pet. App. 77a-78a.

On May 26, 2004, the Ninth Circuit Court of Appeals affirmed, finding the enforcement directive unenforceable:

> A doctor, a pharmacist, several terminally ill patients, and the State of Oregon challenge an interpretive rule issued by Attorney General John Ashcroft which declares that physician assisted suicide violates the Controlled Substances Act of 1970 ("CSA"), 21 U.S.C. §§ 801-904. This so-called "Ashcroft Directive," published at 66 Fed.Reg. 56,607, criminalizes conduct specifically authorized by Oregon's Death With Dignity Act, Or. Rev. Stat. § 127.800-127.897. We hold that the Ashcroft Directive is unlawful and unenforceable because it violates the

> plain language of the CSA, contravenes Congress' express legislative intent, and oversteps the bounds of the Attorney General's statutory authority. *See* 5 U.S.C. § 706(2)(C), (D). * * * .

Pet. App. 2a; see also *id.* at 9a:

> We hold that the Attorney General lacked Congress' requisite authorization. The Ashcroft Directive violates the "clear statement" rule, contradicts the plain language of the CSA, and contravenes the express intent of Congress.

The Ninth Circuit Court of Appeals concluded its analysis as follows:

> In sum, the CSA was enacted to combat drug abuse. To the extent that it authorizes the federal government to make decisions regarding the practice of medicine, those decisions are delegated to the Secretary of Health and Human Services, not to the Attorney General. The Attorney General's unilateral attempt to regulate general medical practices historically entrusted to state lawmakers interferes with the democratic debate about physician assisted suicide and far exceeds the scope of his authority under federal law. We therefore hold that the

> Ashcroft Directive is invalid and may not be enforced.

Id. at 24a.

The Attorney General's enforcement directive

In a two page enforcement directive (Pet. App. 100a-105a) released November 6, 2001, the Attorney General determined the following:

> 1. *Determination on Use of Federally Controlled Substances to Assist Suicide.* For the reasons set forth in the OLC Opinion, *I hereby determine that assisting suicide is not a "legitimate medical purpose"* within the meaning of 21 CFR § 1306.04 (2001), and that prescribing, dispensing, or administering federally controlled substances to assist suicide violates the CSA. Such conduct by a physician registered to dispense controlled substances may "render his registration * * * *inconsistent with the public interest*" and therefore subject to possible suspension or revocation under 21 U.S.C. 824(a)(4). This conclusion applies regardless of whether state law authorizes or permits such conduct by practitioners or others and regardless of the condition of the person whose suicide is assisted.

Pet. App. 102a (emphasis added). The Attorney General directed that his findings be immediately enforced upon publication:

> I hereby direct the DEA, *effective upon publication of this memorandum in the Federal Register*, to enforce and apply this determination, notwithstanding anything to the contrary in the June 5, 1998, Attorney General [Janet Reno]'s letter.

Pet. App. 102a-103a (emphasis added). Consequently, but for the district court's November 8, 2001 restraining order, the enforcement directive would have gone into effect upon publication in the Federal Register on November 9, 2001.

The Attorney General's enforcement threat was limited to Oregon practitioners. *Id.* at 103a (there is "no change in the current standards and practices of the DEA in any State other than Oregon"). The Attorney General further dictated an enforcement strategy. The Oregon Death With Dignity Act[2] imposes statutory record keeping requirements upon practitioners[3] and public reporting requirements upon the Oregon Department of Human Services.[4] The Attorney

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[2] The full text of the Oregon Death With Dignity Act is appended to the Practitioners' Brief in Opposition, 1a-20a ("Practitioners' App.").

[3] See Practitioners' App. 9a-10a (Or. Rev. Stat. § 127.855(1)-(7) (medical record documentation requirements)).

[4] See Practitioners' App. 11a (Or. Rev. Stat. § 127.865(3) (reporting requirements)).

General concluded that those publicly held records should facilitate enforcement proceedings:

> 4. Enforcement in Oregon. * * * . Those records should contain the information necessary to determine whether those holding DEA registrations who assist suicides *in accordance with Oregon law* are prescribing federally controlled substances for that purpose *in violation of the CSA* * * * .

Pet. App. 103a-104a (emphasis added). The Attorney General determined that the DEA had the authority to obtain those records, *id.* at 104a, and concluded his enforcement directive with a distribution instruction in Oregon:

> 5. Distribution. Please ensure that this Memorandum and the OLC opinion on which it is based are promptly distributed to appropriate DEA personnel, *especially those with authority over the enforcement of the CSA in Oregon.*

Id. (emphasis added).

Standing to litigate

Respondents Rasmussen and Hochhalter have standing to challenge the Attorney General's enforcement directive because both have practiced medicine in Oregon and, when appropriate, have prescribed and dispensed controlled

substances under the CSA and Oregon's Death With Dignity Act. See Practitioners' App. 22a-32a (practitioners' affidavits). As such, both are among the primary targets of the Attorney General's enforcement directive and, but for injunctive relief, both are subject to administrative and criminal sanctions pursuant to the Attorney General's enforcement directive.

The State of Oregon is leading a national debate

In *Washington v. Glucksberg*, 521 U.S. 702 (1997), this Court declined to recognize a "generalized" constitutional right to a physician-assisted death.[5] Central to that result was the court's observation that, "the States are currently engaged in serious, thoughtful examinations of physician-assisted suicide and other similar issues." *Id.* at 719. "Our holding permits this debate to continue, as it should in a democratic society." *Id.* at 735. The issue is one that "is entrusted to the 'laboratory' of the States." *Id.* at 737 (O'Connor, J., concurring, joined by Justices Ginsberg and Breyer); see also *id.* at 738 (Stevens, J., concurring) and at 788 (Souter, J., concurring).

Oregon has been at the forefront of this debate. The Oregon Death With Dignity Act was adopted by the people of Oregon at the November 8, 1994 election. Three years later, on November 7, 1997, the people of Oregon decisively rejected, by a margin of 60 percent to 40 percent, a ballot

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[5] Respondents use the term "assisted death" in recognition that "assisted suicide" is still a crime in Oregon. See Or. Rev. Stat. § 163.125 (second degree manslaughter), appended, Practitioners' App. 21a. It is preferable not to use the language of a crime when referring to non-criminal activity.

measure to repeal the Oregon Death With Dignity Act. Two years after that, on June 30, 1999, Governor John Kitzhaber, M.D., signed into law Senate Bill 491, amending the Oregon Death With Dignity Act. As such, the Oregon Death With Dignity Act is a duly enacted state law, twice approved by Oregon voters, subsequently amended by the state legislature and signed into law by Oregon's governor, himself a physician. It is a rare law that has been so thoroughly tested and approved by a state's democratic process.

SUMMARY OF ARGUMENT

Schedule I banned substances are not used under the Oregon Death With Dignity Act, and the Attorney General does not allege that Oregon practitioners are diverting lawful Schedule II substances out of the "closed" system of regulation, from legitimate to illicit channels, or that Oregon practitioners are unlicensed, unregistered, or otherwise unqualified to possess, prescribe, or dispense controlled substances. Consequently, this case has nothing to do with illicit drug use, drug trafficking, or drug diversion.

The Attorney General's interpretative ruling is simply an enforcement directive giving effect to national medical policy, regulating the practice of medicine, and specifically targeting the State of Oregon and DEA registrants practicing under the Oregon Death With Dignity Act. To accomplish his purpose, the Attorney General relies upon a 1984 amendment to the CSA (21 U.S.C. § 823(f)--"public interest") and an agency rule (21 C.F.R. § 1306.04--"legitimate medical purpose"), neither of which empower the Attorney General to regulate the practice of medicine or to impose his preferred medical policies upon the State of Oregon.

The Attorney General substitutes the language of the rule, 21 C.F.R. § 1306.04 ("legitimate medical purpose") for the language of the statute, 21 U.S.C. § 802(21) ("course of professional practice"), and then infuses the word "legitimate" with a subjective, value-laden meaning unsupported by the legislative record. Congress, however, never intended that the Attorney General would pass judgment on the "legitimacy" of medical policy in the States in the absence of illicit drug use, drug trafficking and drug diversion.

The Attorney General also removes his authorities from their proper context. Unlike the drug-dealing physicians in the *Rosenberg*, *Moore*, and *Rosen* cases, for example, there is no allegation by the DOJ or the DEA that physicians practicing under the Oregon Death With Dignity Act are diverting drugs from legitimate to illicit channels. Rather, both the DOJ and the DEA concede that Oregon practitioners are practicing in accordance with Oregon law, and that the drugs are used for their intended purpose within the closed system of regulation. Consequently, there is no illicit drug use, no drug trafficking, and no drug diversion. No law is broken. No crime is committed. Not even the community standard of care is violated.

The express language of the CSA, the case law interpreting the CSA, and the legislative record in support of the CSA, all make clear that the Attorney General's proper role is to regulate the manufacture, dispensing and distribution of controlled substances to prevent illicit drug use, trafficking, and diversion. Aside from encouraging drug education, research, and rehabilitation, the CSA serves a law-enforcement purpose and no other purpose. Nothing contained in the CSA gives the Attorney General direct control over the practice of medicine in the States, nor could

it. See, *e.g.*, *Linder v. United States*, 268 U.S. 5, 18 (1924) ("Obviously, direct control of medical practice in the States is beyond the power of the Federal Government"); *Barsky v. Board of Regents*, 347 U.S. 442, 449 (1953) ("It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power"); *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 387 (2002) (determination of medical necessity and standards of reasonable care are "quintessentially state-law" determinations).

Not only must the Attorney General persuade this Court that his interpretation of the CSA is correct, he must further demonstrate that it was the intent of Congress to alter the state/federal framework--in this case, by permitting federal encroachment into the practice of medicine, an area of traditional State concern. He fails on both counts.

The Attorney General's bias was exposed in the Ninth Circuit Court of Appeals below when he framed the issue as "healing, not killing." Appellants' Brief, 11. Once the Attorney General's argument is exposed for what it is--a policy disagreement with the State of Oregon over the practice of medicine, and not a disagreement over the enforcement of the CSA to prevent illicit drug use, drug trafficking, or drug diversion--the inquiry should be over.

Finally, the power to regulate commerce between the States does not permit federal control over the manner in which Oregonians die, the choices they possess when facing death, the scope of state criminal laws prohibiting assisted suicide, or state health-care laws permitting a physician-assisted death.

ARGUMENT

I. The Attorney General's enforcement directive violates the plain language of the Controlled Substances Act, oversteps the bounds of the Attorney General's statutory authority, and contravenes Congress' express legislative intent.

The Controlled Substances Act, 21 U.S.C. §§ 801-950, controls certain delineated substances by first classifying them and then setting restrictions on each class of substance. These restrictions apply to the manufacture, distribution, sale, possession, and use of such substances. The classifications range from schedule I substances, which have no recognized medical use and are therefore banned except in very limited research contexts, to schedule II, III, IV and V substances, which have recognized uses and can be manufactured, distributed, possessed and used, subject to the restrictions of the CSA. As this Court recently explained:

> the CSA, repealed most of the earlier antidrug laws in favor of a comprehensive regime to combat the international and interstate traffic *in illicit drugs. The main objectives of the CSA were to conquer drug abuse and to control the legitimate and illegitimate traffic* in controlled substances. * * * Congress was particularly concerned with *the need to prevent the diversion of drugs from legitimate to illicit channels.* * * * .

> To effectuate these goals, Congress devised *a closed regulatory system* making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. 21 U.S.C. §§ 841(a)(1), 844(a).

Gonzales v. Raich, 125 S.Ct. 2195, 2203 (2005) (emphasis added, footnotes omitted); citing 21 U.S.C. §§ 801(1)-(6) (Congressional findings); *United States v. Moore*, 423 U.S. 122, 135 (1975); H.R. Rep. No. 91-1444, pt. 2, p. 22 (1970).

In *Gonzales v. Raich*, this Court very recently upheld the power of Congress to classify marijuana as a schedule I banned substance. Unlike in *Raich*, however, there is no allegation in the instant case that a schedule I banned substance is being used under the Oregon Death With Dignity Act.[6] Nor does the Attorney General allege that Oregon practitioners are diverting lawful Schedule II substances out of the "closed" system of regulation, from legitimate to illicit channels, or that Oregon practitioners are unlicensed, unregistered, or otherwise unqualified to possess, prescribe, or dispense controlled substances.

The Attorney General instead argues that although "schedule II substances have *other* generally accepted medical

[6] The Attorney General readily concedes that schedule II substances are used under Oregon's unique law. See Pet. App. 132a, n.25; see also Pet. Br. 29, n.11 ("the three drugs that have been dispensed pursuant to the DWDA are secobarbital, pentobarbital, and amobarbital, all of which are schedule II depressants").

uses in treatment, deliberately assisting a person to commit suicide is not one of them." Pet. Br. 30 (italics in original, underscore added). In support of his position, the Attorney General invokes what he describes as a "broad consensus" evidenced by "centuries of almost uniform opposition" and "the law of 49 of the 50 States." Pet. Br. 18.

The Attorney General locates in the CSA each use of the words "legitimate" and "treatment" and concludes that he is empowered under the CSA to judge whether a specific medical practice is legitimate, Pet. Br. 18-24, even in the absence of illicit channels of distribution, drug trafficking, or drug diversion, and regardless of state law and the medical standard of care.

The Attorney General cites four authorities (Pet. Br. 25-26) in support of his "national standards" argument (Pet. Br. 26-37) that when Congress enacted the CSA, it "believed [that] *medical judgments* could and should be made *on the national level*." Pet. Br. 27 (emphasis added). The Attorney General relies upon cases that interpret "maturity," as used in the Security Exchange Act of 1934; "stolen," as used in the National Motor Vehicle Theft Act; "future interests," as used in the Revenue Act of 1932; and "domicile," as used in the Indian Child Welfare Act. Pet. Br. 25. In none of these cases, however, did a federal agency seek through application of an agency rule (21 C.F.R. § 1306.04--"legitimate medical purpose") to so drastically alter the meaning of a statute, or to expand a federal agency's power to regulate medicine, an area of traditional state concern.

Although Congress provided immunity from criminal prosecution to physicians and pharmacists who prescribe, possess, and dispense controlled substances "in the course of

professional practice" (21 U.S.C. § 802(21)), the Attorney General instead relies upon a fragment of an agency rule, *i.e.*, that pursuant to 21 C.F.R. § 1306.04, a prescription for a controlled substance must be issued for a "*legitimate medical purpose*."[7] See Pet. App. 102a (enforcement directive). The Attorney General places a particularly strong emphasis on the word "legitimate" and, by the time he is through with his interpretation of the rule, any deference to the practice of medicine under the "course of professional practice" standard, or to the States to regulate medicine, is subsumed by the Attorney General's inquiry into the legitimacy of Oregon's medical policy. Although he fails to allege drug trafficking, drug diversion, or the use of schedule I banned substances, the Attorney General has nonetheless construed an agency rule so as to empower the DEA to investigate, prosecute and convict both respondents for what amounts to a violation of the national medical policy he espouses in his enforcement directive.

A. Medical practice under the Oregon Death With Dignity Act establishes the "course of professional practice."

When the State of Oregon adopted its Death With Dignity Act in 1994, it created a narrow exception to its penal code prohibiting assisted suicide[8] and also codified a new

[7] 21 C.F.R. § 1306.04 provides in relevant part, "[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice * * * ."

[8] See Or. Rev. Stat. § 163.125 (second degree manslaughter), appended, Practitioners' App. 21a.

standard of care regarding medical treatment near the end of life,[9] two areas of traditional State concern.

The question for the Attorney General under the CSA is whether Oregon practitioners are practicing in the "course of professional practice" (21 U.S.C. § 802(21)), or for a "medical purpose." *United States v. Moore*, *supra*, 423 U.S. at 137, n.13. This Court's review of generally accepted medical practices in *Moore* was limited to effectuating the "course of professional practice" standard, a screening device to detect drug diversion. Unlike in *Moore*, however, the Attorney General does not allege a single incident of drug diversion. And unlike in *Raich*, which involved the medical use of marijuana, the Attorney General does not allege a single use of a schedule I banned substance.

The Oregon Death With Dignity Act is a "prescribing law" only. Only Schedule II and lower drugs are prescribed. Oregon's novel law expressly prohibits "lethal injection, mercy killing [and] active euthanasia"[10] and requires that practitioners be licensed by the state Board of Medical

[9] See Or. Rev. Stat. 127.800 *et seq.* (Oregon Death With Dignity Act), appended, Practitioners' App. 1a-20a.

[10] Or. Rev. Stat. § 127.880 provides as follows:

> **Construction of Act.** Nothing in ORS 127.800 to 127.897 shall be construed to authorize a physician or any other person to end a patient's life by lethal injection, mercy killing or active euthanasia. Actions taken in accordance with ORS 127.800 to 127.897 shall not, for any purpose, constitute suicide, assisted suicide, mercy killing or homicide, under the law. [1995 c.3 §3.14]

Examiners and registered with the DEA. See Or. Rev. Stat. § 127.815(1)(L)(A), appended, Practitioners' App. 7a. The role of an attending physician is limited to caring for the patient and ensuring that all medical and legal criteria are satisfied before prescribing or dispensing controlled substances for use by the patient. Subsection 815(1)(k) provides, for example, that:

> (1) The attending physician shall: * * * (k) Ensure that all appropriate steps are carried out in accordance with ORS 127.800 to 127.897 prior to writing a prescription for medication to enable a qualified patient to end his or her life in a humane and dignified manner * * * .

Or. Rev. Stat. § 127.815(1)(k).

Dr. Rasmussen has demonstrated on this record that he and others like him practicing under the Oregon Death With Dignity Act are acting in their professional capacities in conformity with state law and the medical standard of care. In support of his request for permanent relief, Dr. Rasmussen averred that:

> 9. Prior to [the district] court's issuance of a temporary restraining order, my ability to meet the *community standard of care as established under Oregon law and practice* was severely restricted. As the direct result of th[e district] court's preliminary injunctive relief, my ability

> to meet the *community standard of care as established under Oregon law and practice* has been restored.

Practitioners' App. 24a, ¶ 9 (Rasmussen affidavit, emphasis added). Similarly, Dr. Rasmussen averred:

> 16. * * * . Due to Attorney General John Ashcroft's directive to enforce the Controlled Substances Act against physicians like myself practicing *in accord with Oregon law and the community standard of care*, and in the absence of a permanent injunction, I will no longer be able to meet the *community standard of care as established under Oregon law and practice*. I cannot risk DEA registration revocation proceedings or other sanctions, criminal and financial. I cannot risk my ability to practice as a medical oncologist, which has provided my livelihood for 21 years. Nor can I risk my family's security, or my ability to provide for my family.

See Practitioners' App. 26a, ¶ 16 (Rasmussen affidavit, emphasis added).

Only controlled substances are suitable for use under the Oregon Death With Dignity Act:

> 17. In the absence of a permanent injunction, the Oregon

Death With Dignity Act will be rendered useless. *Only controlled substances are suitable for use under the Oregon Death With Dignity Act*; they are used for what Oregon has determined to be *a legitimate medical purpose in the normal course of medical practice in Oregon*. These controlled substances are prescribed by physicians and dispensed by pharmacies for other purposes as well. Prescriptions for controlled substances under the Oregon Death With Dignity Act are written by state-licensed physicians and filled by state-licensed pharmacists, in full compliance with the closed system of procedures established by the CSA and enforced by the DEA. *These drugs are not otherwise available.*

See Practitioners' App. 26a-27a, ¶ 17 (Rasmussen affidavit, emphasis added).

As expressly required under the Oregon Death With Dignity Act, see Or. Rev. Stat. § 127.815(1)(L)(A), Dr. Rasmussen is registered with the state Board of Medical Examiners *and* the DEA. See Practitioners' App. 22a ¶¶ 1-2 (Rasmussen affidavit).

The standard of care for the attending physician practicing under the Oregon Death With Dignity Act is set out at Or. Rev. Stat. § 127.815 (attending physician responsibilities), appended, Practitioners' App. 5a-7a.

Consistent with those numerous statutory requirements, Dr. Rasmussen makes an initial determination of whether his patient has a terminal disease, is capable, and has made the request voluntarily. Dr. Rasmussen ensures that his patient is making an informed decision by informing the patient of the patient's medical diagnosis, prognosis, the potential risk and probable result associated with taking the medication to be prescribed, and the feasible alternatives, including, but not limited to, comfort care, hospice care and pain control. Dr. Rasmussen further refers his patients to a consulting physician for medical confirmation of his diagnosis and for a second opinion that the patient is capable and acting voluntarily. When appropriate, Dr. Rasmussen also refers his patients for counseling. He recommends that the patient notify next of kin and counsels the patient about the importance of having another person present when the patient takes the medication prescribed under Oregon law. See Practitioners' App. 24a-25a, ¶¶ 10-11 (Rasmussen affidavit).

As further required by Oregon's statutory standard of care, Dr. Rasmussen dispenses the medications directly, including ancillary medications intended to facilitate the desired effect and minimize the patient's discomfort or, in the alternative, Dr. Rasmussen contacts a pharmacist and informs the pharmacist of the prescription, and he then delivers the written prescription personally or by mail to the pharmacist, who will dispense the medications to either the patient, the attending physician, or the patient's chosen agent. See Practitioners' App. 25a ¶ 12 (Rasmussen affidavit).

Dr. Rasmussen further satisfies all of the statutory medical documentation requirements and provides a copy of his dispensing record to the Department of Human Services. In sum, Dr. Rasmussen ensures that all appropriate steps are

carried out in accordance with Or. Rev. Stat. § 127.800 to 127.897 (see Practitioners' App. 25a, ¶ 13), as is required of him under state statutory and regulatory law, and the community standard of care. See, *e.g.*, Or. Rev. Stat. § 127.815. Dr. Rasmussen is at all times practicing medicine, acting for a medical purpose:

> 13. * * * . I comply with all the provisions of the Oregon Death With Dignity Act. I never engage in drug trafficking or diversion. As a physician practicing under the Oregon Death With Dignity Act, I am practicing *legitimate medicine in the course of my professional practice.*

See Practitioners' App. 25a, ¶ 13 (Rasmussen affidavit, emphasis added).

B. Criminal proceedings under the Controlled Substances Act; drug trafficking, drug diversion, and the "course of professional practice."

The CSA establishes both criminal and administrative recourse against those who violate its provisions. In a criminal prosecution to convict a DEA registered practitioner of unlawful distribution, the government must prove beyond a reasonable doubt that the practitioner:

(1) knowingly or intentionally;
(2) prescribed or dispensed a controlled substance;
(3) outside the course of professional practice.

These three elements of the crime are derived from the circular structure of the CSA.[11] The crime of unlawful distribution is a specific intent crime--the practitioner must have specifically intended ("knowingly or intentionally") to commit a criminal act.[12] This *mens rea* requirement applies to the second element (distribution) and to the third element (outside the course of professional practice).[13] It is not

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[11] It is a crime to (1) knowingly or intentionally (2) distribute or dispense a controlled substance unless "authorized" by the Act. See 21 U.S.C. § 841(a). Authorization is obtained by "registering" with the Attorney General. See 21 U.S.C. § 822(a)(2). Persons registered with the Attorney General are authorized to possess, manufacture, distribute, or dispense controlled substances to the extent authorized by their registration. See 21 U.S.C. § 822 (b). Physicians and pharmacists licensed by a state and registered with the Attorney General are "practitioners," and, as such, they are authorized to dispense controlled substances (see 21 U.S.C. § 829(a)&(b)) in "the course of [their] professional practice." See 21 U.S.C. § 802(21); see also *United States v. Moore*, 423 U.S. 122, 140 (1975).

[12] See, *e.g.*, 21 U.S.C. § 841(a); see also *United States v. Brower*, 336 F.3d 274, 276 (4th Cir. 2003) ("The Government's mens rea burden is defined under § 841(a), which makes it an offense to 'knowingly or intentionally' distribute a controlled substance"); *United States v. King*, 345 F.3d 149, 153 (2nd Cir. 2003) (" * * * § 841(a) contains a *mens rea* requirement: The trier of fact must determine that the defendant 'knowingly or intentionally' manufactured, distributed, dispensed, or possessed with intent to distribute a schedule I or II controlled substance").

[13] In *Arthur Andersen, LLP v. United States*, 125 S.Ct. 2129, 2135 (2005), this Court recently explained:

> We have recognized with regard to similar statutory language that the *mens rea* at least applies to the acts

(continued...)

enough to prove beyond a reasonable doubt that a practitioner knowingly or intentionally distributed a controlled substance, for *all* practitioners who prescribe or dispense controlled substances intend that much. Rather, it must be proven beyond a reasonable doubt that the practitioner intentionally departed *the course of professional practice--i.e.,* that the physician was no longer practicing medicine--but instead dealing drugs.[14]

In sharp contrast, the phrase "legitimate medical purpose" is not the value-laden phrase the Attorney General portrays it to be,[15] and the Attorney General misconstrues this Court's decision in *United States v. Moore*, when he argues as follows:

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[13](...continued)
that immediately follow, if not to other elements down the statutory chain.

[14] In *Arthur Andersen, supra*, this Court stressed the importance of, "limiting criminality * * * to reach only those with the level of 'culpability * * * we usually require in order to impose criminal liability.'" 125 S.Ct. at 2136; quoting *United States v. Aguilar*, 515 U.S. 593, 602 (1995).

[15] See, *e.g.*, Pet. Br. 10-11 (that "physician-assisted suicide is not a legitimate medical purpose is well supported by an 'overwhelming historical, legal, and medical consensus'"); 23 ("In light of the historical unanimity of opinion on this issue, and the fact that the CSA predated Oregon's DWDA by several decades, it is inconceivable that Congress, in enacting the CSA, regarded assisted suicide as a legitimate 'medical' practice in the 'treatment' of disease"); 23 ("Numerous health care experts have likewise agreed that physician-assisted suicide is not a legitimate medical treatment"); 24 ("In other federal laws and programs as well, physician-assisted suicide is not regarded as a legitimate medical practice").

> As this Court noted in *Moore*, the requirement that a controlled substance be prescribed for a *legitimate medical purpose* may be implicit in various provisions of the CSA, such as 21 U.S.C. 829, but is, in any event, made explicit by virtue of the implementing regulation, 21 C.F.R. 1306.04(a). See *Moore*, 423 U.S. at 137-139 & n.13.

Pet. Br. 5 (emphasis added). Correctly stated, however, this Court in *Moore* said:

> The *medical purpose requirement* explicit in subsection (c) could be implicit in subsections (a) and (b). Regulation § 306.04 makes it explicit.

Moore, 423 U.S. at 137, n.13 (emphasis added). The Attorney General has thus transformed "medical purpose," a phrase not inconsistent with the statutory phrase "course of professional practice," into the value laden term that he prefers, "legitimate medical purpose." This Court in *Moore* never went so far, and a simple word search indicates that the phrase "legitimate medical purpose" was used only one time, in footnote 12, when this Court quoted the text of 21 CFR § 1306.04(a) (formerly, § 306.04). See *Moore*, 423 U.S. at 136-137, n.12.

The Attorney General repeatedly removes *Moore* from its proper context. In *Moore*, this Court held that a physician who acts as a "'pusher'--not as a physician," violates the

CSA. *Id.* at 143.[16] *Moore* involved a physician who was convicted for drug diversion in violation of 21 U.S.C. § 841. The court of appeals overturned the conviction, holding that, "a physician registered under the Act is *per se* exempted from prosecution under § 841 because of his status as a registrant." *Id.* at 131. This Court reversed, holding that, "only the lawful acts of registrants are exempted." *Id.* The legislative history of the CSA, explained the Court, "indicates that Congress was concerned with the nature of the *drug transaction*, rather than with the status of the defendant." *Id.* at 134 (emphasis added). Citing the House Report, the Court concluded that a violation of the CSA, "was intended to turn on whether the '*transaction*' falls within or without *legitimate channels*." *Id.* at 135 (emphasis added). This Court explained that "[t]he evidence presented at trial was sufficient for the jury to find that [Dr. Moore's] conduct exceeded the bounds of 'professional practice.'" *Id.* at 142. That evidence, explained the Court, was sufficient to convince the jury that Dr. Moore "acted as a large-scale 'pusher'--not as a physician." *Id.* at 143. Thus, the Court equated acting

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[16] This Court summarized Dr. Moore's conduct as follows:

> [Dr. Moore] gave inadequate physical examinations or none at all. He ignored the results of the tests he did make. He did not give methadone at the clinic and took no precautions against its misuse and diversion. He did not regulate the dosage at all, prescribing as much and as frequently as the patient demanded. He did not charge for medical services rendered, but graduated his fee according to the number of tablets desired. In practical effect, he acted as a large-scale "pusher"-not as a physician.

United States v. Moore, 423 U.S. 122, 142-143 (1975).

outside "the bounds of professional practice" with acting as a "pusher," diverting drugs outside of legitimate channels.

In *Moore*, this Court also described the "closed system" of regulation established by the CSA, *i.e.*, "Congress was particularly concerned with the diversion of drugs from *legitimate channels to illegitimate channels*." *Id.* at 135 (citing the House Report, emphasis added). Under the scheme fashioned by Congress, "[i]nstead of expressly removing from the protection of the Act those physicians who operate beyond the bounds of professional practice, the CSA uses the concept of 'registration.'" *Id.* at 140. The federal registration "contemplates that [the physician] is *authorized by the State to practice medicine* and to dispense drugs in connection with his professional practice." *Id.* at 141 (emphasis added). The federal registration, explained the Court, "extends no further. It authorizes transactions within 'the *legitimate distribution chain*' and makes all others illegal." *Id.* (emphasis added). Implicit in a physician's registration, "is the understanding that he is authorized only to act 'as a physician.'" *Id.* This understanding reflects Congressional recognition that "registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for *diversion*, were responsible for a large part of the illegal drug traffic." *Id.* at 135 (emphasis added).

Thus the question, whether a physician is prescribing in the course of his or her professional practice, simply asks whether the controlled drugs remain within the "closed system," or within "legitimate channels" or with a "legitimate distribution chain." A review of the case law interpreting the phrase, "course of professional practice," including *Moore, supra*, further reveals that until recently DEA enforcement activity has focused exclusively upon drug abuse or diversion

flowing from egregious departures from the course of professional practice.

In *United States v. Collier*, 478 F.2d 268 (5th Cir. 1973), the court equated "the course of professional practice" to "within the bounds of professional practice," or the opposite of the physician as drug pusher:

> Manifestly the language "in the course of professional practice" is intended to limit the immunity of a licensed practitioner. It is apparent that a licensed practitioner is not immune from the act solely due to his status * * * but rather because he is expected to prescribe or dispense drugs *within the bounds of his professional practice of medicine*. * * * . However, under the guise of treatment a physician cannot sell drugs to a dealer nor distribute drugs intended to cater to cravings of an addict. * * * *Congress did not intend for doctors to become drug "pushers."*

Collier, 478 F.2d at 271-72 (emphasis added). In *United States v. Rosen*, 582 F.2d 1032 (5th Cir. 1978), the court acknowledged the difficulty of direct application of the *Collier* interpretation in close-call cases, prompting the court to describe its dilemma this way:

> Our facile quotation of general principle does not diminish the difficulty in its application. A majority

> of cases have dealt with facts which were so blatant that a statement of clear cut criteria in a form useful in other cases would have been superfluous to the decision. We are, however, able to glean from reported cases certain recurring concomitance of condemned behavior, examples of which include the following [nine factors.]

Rosen, 582 F.2d at 1035-36. The *Rosen* court then listed nine behaviors from the case law that may be present when a physician is diverting drugs, *i.e.*, practicing medicine outside the "course of professional practice," as follows:

1. An inordinately large quantity of controlled substances was prescribed;
2. Large numbers of prescriptions were issued;
3. No physical examination was given;
4. The physician warned the patient to fill prescriptions at different drug stores;
5. The physician issued prescriptions to a patient known to be delivering the drugs to others;
6. The physician prescribed controlled drugs at intervals inconsistent with legitimate medical treatment;
7. The physician involved used street slang rather than medical terminology for the drugs prescribed;
8. There was no logical relationship between the drugs prescribed and treatment of the condition allegedly existing; and

9. The physician wrote more than one prescription on occasions in order to spread them out.

Rosen, 582 F.2d at 1036.

Both *Collier* and *Rosen* demonstrate that even in cases involving "close call" medical judgment, the only relevant issue under the CSA is whether legitimate drugs are being diverted into illicit channels. When the courts compare the practitioner's conduct against professional practice standards, the only purpose is to screen for diversion of controlled substances; the "course of professional practice" standard, 21 U.S.C. § 802(21), is simply a screening device intended to preserve the closed system of regulation. See also *Humphreys v. DEA*, 96 F.3d 658, 666 (3rd Cir. 1996) (reversing DEA's decision to revoke a physician's registration because the evidence proffered by DEA showed that the potential for diversion "is so unlikely as to be unsustainable"); *United States v. Rosenberg*, 515 F.2d 190, 197, 199 (9th Cir. 1975) (affirming conviction based on the jury's finding, "that Dr. Rosenberg was not acting in the course of his professional practice" after the jury was instructed that the CSA was violated if Dr. Rosenberg, "was not acting in good faith as a doctor, but simply pushing pills"). Remarkably, in the instant case, the Attorney General fails to allege a single violation of the closed system of regulation, and instead invokes 21 C.F.R. § 1306.04 as authority to pass judgment on the "legitimacy" of medical policy in the States. The rule and the statute, however, mean the same thing, *Moore*, 423 U.S. at 137, n.13. In other words, a prescription is written for a "medical purpose" if it is written in the "course of professional practice." *Id.* If there is any disagreement between the rule and the statute, the rule must give way to the statute.

C. Administrative proceedings under the Controlled Substances Act; revocations, denials, and the "public interest."

A violation of the "course of professional practice" standard is also actionable in administrative proceedings.[17] Although, in an administrative proceeding, the burden of proof is lower and the sanctions less severe, the meaning of the phrase "course of professional practice" remains the same, rendering further analysis of this phrase unnecessary.

In an administrative context, however, the Attorney General goes one step further and concludes as a matter of law that medical practice under the Oregon Death With Dignity Act is not in the "public interest," thereby empowering the DEA to revoke existing registrations and deny new applications.

The impact upon medicine in the State of Oregon is undeniable. The Oregon Death With Dignity Act requires that practitioners possess a DEA registration and, as this record makes clear, schedule II drugs are not only used under the Oregon Death With Dignity Act, they are also necessary, and there are no substitutes. See discussion *supra*, 12, n.6 & 17-18. Consequently, the power to revoke or deny the DEA registrations of those who practice under the Oregon Death With Dignity Act is the power to regulate medicine in Oregon.

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[17] See, *e.g.*, *William J. Roth, M.D.*, 60 Fed. Reg. 62262 (1995); *William F. Skinner, M.D.*, 60 Fed. Reg. 62887 (1995); *Paul W. Saxton, D.O.*, 64 Fed. Reg. 25073 (1999); *Wesley G. Harline, M.D.*, 65 Fed. Reg. 5665 (2000).

The Attorney General's role in construing the "public interest" flows from a 1984 amendment to the CSA. It is not, however, the expansive grant of power that the Attorney General portrays it to be. Congress, once again concerned about the diversion of controlled substances from legitimate to illicit channels by physicians and pharmacists who had easy access via their DEA registrations, sought to give the Attorney General more leeway when issuing and revoking DEA registrations. Congress was motivated by the fact that the States were often slow to take action. The solution, aptly named, was the Dangerous Drug Diversion Control Act of 1984, the relevant section of which is now codified at 21 U.S.C. § 823(f)(1)-(5), under which section the Attorney General is empowered to deny, "an application for * * * registration if he determines that the issuance of such registration would be inconsistent with the *public interest*." 21 U.S.C. § 823(f) (emphasis added). The Attorney General's power to construe the public interest is narrowly circumscribed, however. Congress mandated that when "determining the public interest," the Attorney General "shall" consider the following five factors:

> (1) The recommendation of the appropriate *State licensing board or professional disciplinary authority*.
>
> (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
>
> (3) The applicant's *conviction record under* Federal or *State laws* relating to the manufacture, distribution, or dispensing of controlled substances.

> (4) *Compliance with applicable State*, Federal, *or local laws* relating to controlled substances.
>
> (5) Such other conduct which may threaten the public health and safety.

21 U.S.C. § 823(f)(emphasis added).[18] As such, the Attorney General's discretion to determine the "public interest" has clear limits. Although the phrase "public interest" is itself broad and abstract, Congress dictated five criteria that "shall" be considered when determining the public interest under the CSA. *Id.* Three of those criteria direct the Attorney General to consult state law. 21 U.S.C. § 823(f)(1),(3)&(4). The remaining two subsections, although not expressly referencing state law, certainly include state law. 21 U.S.C. § 823(f)(2)&(5). Inasmuch as the 1984 amendment was partially in response to the perceived slow action of the States, the five factors set out in 21 U.S.C. § 823(f)(1)-(5) are best viewed as placing the Attorney General "in the shoes" of the State, to empower the Attorney General to make a determination similar to a State's determination, had the State acted first. In no event does § 823(f)(1)-(5)

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[18] A corresponding amendment was made to 21 U.S.C. § 824(a), which applies to the *revocations* of § 823 *registrations*, listing five "grounds" for revocation. The criteria for revocation differ from the criteria applicable when granting an initial registration, except that § 824(a)(4) incorporates by reference the § 823(f) "public interest" requirement. Consequently, the public interest is relevant to both initial registrations and subsequent revocations.

empower the Attorney General to ignore or reject state law, as he has in the instant case.[19]

The Attorney General's desire to reject state law is further remarkable in view of the fact that during the first 14 years of the CSA, the only thing that mattered was the practitioner's compliance with state law:

> *Practitioners shall be registered* to dispense * * * controlled substances in schedule II, III, IV, or V *if they are authorized to dispense or conduct research under the law of the State in which they practice.* * * * .
>
> *Pharmacies* (as distinguished from pharmacists) when engaged in commercial activities, *shall be registered* to dispense controlled substances in schedule II, III, IV, or V *if they are authorized to dispense under the law of the State in which they regularly conduct business.*

Former 21 U.S.C § 823(f) (emphasis and paragraphing added); see also, *Moore*, 423 U.S. at 140-141 ("Registration of physicians and other practitioners * * * is mandatory if the applicant is authorized to dispense drugs or conduct research under the law of the State in which he practices"). The *Moore* decision relied upon the House Report explanation that DEA registration is "a matter of right" where the practitioner is using the controlled substances in compliance with state law:

> The House Report described the rationale behind § 823(f) as follows: "Practitioners * * * engaged in the distribution chain would be required to be registered, but *registration would be as a matter of right where the individual or firm is engaged in activities involving these drugs which are authorized or permitted under State law* * * * ."

Id. at 141, n.19 (emphasis added). Prior to the 1984 amendment, then, the Attorney General's role was clerical, limited to issuing DEA registrations so long as the applicant was authorized under state law. Consequently, it is an amazing contention by the Attorney General today that, as a result of a 1984 amendment, he is newly empowered to reject state law and exert *de facto* control over the practice of medicine in the States when, prior to 1984, he had no choice but to follow state law.

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[19] Limiting the "public interest" clause, as well as the catchall provision found in subsection (f)(5) ("such other conduct") to the consideration of federal, state and local law is consistent with the maxim, *ejusdem generis*:

> the statutory canon that "where general words follow specific words in a statutory enumeration, the general words are construed to embrace only objects similar in nature to those objects enumerated by the preceding specific words."

Circuit City Stores, Inc. v. Adams, 532 U.S 105, 114-115 (2001); quoting, 2A N. Singer, *Sutherland on Statutes and Statutory Construction* § 47.17 (1991).

D. The Congressional record establishes that the Controlled Substances Act is an anti-drug law-enforcement statute, not a medical practices act

The legislative record demonstrates that the CSA is a law-enforcement statute and that Congress never intended that it would be used to regulate medicine or to alter the state/federal framework. The following excerpts from the 1970 Senate floor debate reveal that the CSA was at first focused solely upon preventing drug trafficking and diversion; it served a law-enforcement purpose and no other purpose:

> This measure--in concept, in spirit, and in detail--*is a law-enforcement measure.* It only approaches one side of the problem of drug abuse.

Quoting Senator Hughes, 116 Cong. Rec. 973 (1970) (emphasis added).

> That is my position on this problem. The legislation before us is a *law enforcement bill.* * * * we concluded it would be better to keep this particular piece of legislation *a law enforcement measure.*

Quoting Senator Dodd, 116 Cong. Rec. 976 (1970) (emphasis added).

> The proposed legislation provides a regulatory schedule for the lawful manufacture, distribution, and

> dispensing of controlled drugs to furnish us with better law enforcement tools *so that the rampant drug abuse problem can finally be curbed* effectively.

Quoting Senator Dodd, 116 Cong. Rec. 978 (1970) (emphasis added).

> But it cannot be overemphasized that the bill before the Senate today is *entirely concerned with enforcement.* It contains no medical or rehabilitative provisions.
>
> It is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls. * * * .

Quoting Senator Dodd, 116 Cong. Rec. 978 (1970) (emphasis added).

> * * * this title reaffirms the Federal Government's role in drug control. Basically this role is to regulate the legitimate drug trade *to prevent diversion of medically useful dangerous drugs into illegitimate channels and to help reduce the criminal traffic* in all narcotic and dangerous drugs on the local, national, and international level.

Quoting Senator Dodd, 116 Cong. Rec. 996 (1970) (emphasis added).

> *All of these provisions are designed to reduce the diversion of drugs* from the legitimate course of commerce and use *into illegal channels*. This is important in the face of evidence that about half of the annual production of amphetamine and barbiturate drugs, or between 8 and 9 billion pills, *have been diverted to nonmedical use*.

Quoting Senator Dodd, 116 Cong. Rec. 996 (1970) (emphasis added).

The debate changed little as it moved to the House. The primary difference was that the House expanded the legislation to include drug research, education and treatment, in addition to the Senate's narrower focus upon the prevention of drug trafficking and diversion. The entire debate remained, however, in the context of the drug problem:

> There are a limited number of approaches to attack this problem—preventive steps, aimed at stopping experimentation before it starts; control, to regulate the supply and availability of drugs; rehabilitation to lead individuals away from drug dependence and addiction. It is my conviction that the Federal Government must make a concentrated effort in all of these areas.

Quoting Representative Boland, 116 Cong. Rec. 33,315 (1970).

> The word "control" in the title, of course, simply means enforcement by the Justice Department in *problems related to drug abuse*, by any person or corporation whether a manufacturer, wholesaler, or retailer. These controls cover all the hard narcotics and opiates, marihuana, and hallucinogens such as LSD, amphetamines, barbiturates, and even any tranquilizers subject to abuse.

Quoting Representative Randall, 116 Cong. Rec. 33,656 (1970) (emphasis added).

Here again, nothing from the 1970 House floor debate remotely suggests that Congress intended the Attorney General to determine the "legitimacy" of medicine, or to establish medical policy in the States. To better control the rampant drug problem, the House expanded the reach of the CSA to include drug research, education, treatment, and rehabilitation, but included not a word about regulating medical practice. The relevant language in the proposed legislation did not significantly change when it returned to the Senate later that same year:

> I am particularly grateful that the basic Controlled Dangerous Substances Act was passed in almost its entirety by the House. There were a number of minor disagreements; but more than 90 percent of the law which was reported by the Senate

> Subcomittee [sic] on Juvenile Delinquency will soon become the law of the land.
>
> .
>
> This is no mean achievement. The Senate legislation passed the very close scrutiny of the House[,] which investigated the bill for many months. No significant changes were made, a procedure which does not often occur in bills sent over from the Senate.

Quoting Senator Dodd, 116 Cong. Rec. 35,051-52 (1970).

Fourteen years later, the 1984 amendments reveal that once again Congress was concerned about a rampant drug abuse problem, the diversion of otherwise lawful drugs to illicit or recreational uses. The bill was aptly named the Dangerous Drug Diversion Control Act of 1984 and it was described as follows:

> Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 5656) to amend the Controlled Substances Act *to strengthen the authority to prevent diversion of controlled substances*, and for other purposes, as amended.

Quoting Representative Hughes, 130 Cong. Rec. 25,846 (1984) (emphasis added).

> This bill addresses one of the most critical areas of drug abuse, the abuse of prescription drugs. Prescription drugs are responsible for close to 70 percent of the deaths and injuries due to drug abuse. But I am sorry to say this aspect of drug abuse, *the diversion problem*, has often failed to get the societal or the enforcement attention that it deserves.

Quoting Representative Hughes, 130 Cong. Rec. 25,848 (1984) (emphasis added). The Attorney General would likely take the "deaths and injuries" phrase above out of context, just as he does in his petition and brief (see Pet. Cert. 23; Pet. Br. 45: "misuse of a drug in suicides and attempted suicides"), but the Congress was only concerned with *illicit use* flowing from "diversion":

> *Diversion* is the connotation for the various means by which legitimate medical controlled substances are diverted from proper use to improper use. Invalid prescriptions and pharmacy robberies are two types of retail level *diversion*. While much of the drug enforcement focus has been placed on the interdiction of improperly imported substances, *the problem of domestic diversion has quietly grown to staggering proportions*.
>
> * * * . Abuse of prescription drugs through *diversion* at the manufacturing and distribution levels [is] severely

> curtailed under current law by DEA. The vast majority of *diversions* occur at the retail level. * * * .
>
> * * * * *
>
> * * * . *This bill provides the Drug Enforcement Agency with the necessary tools to join State agencies in reducing diversion.*

Quoting Representative Sawyer, 130 Cong. Rec. 25,849 (1984) (emphasis added).

> Mr. Speaker, I rise in strong support of H.R. 5656, the *Dangerous Drug Diversion Control Act* of 1984. The bill amends the Controlled Substances Act to attempt *to prevent the diversion of controlled substances from legitimate channels of medical distribution and administration to illegitimate channels for purposes of abuse.* Evidence suggests that prescription drugs *diverted* by legitimate medical distributors to the illicit drug market accounts for about three-fourths of deaths and injuries due to drug abuse.

Quoting Representative Gilman, 130 Cong. Rec. 25,851 (1984) (emphasis added).

In sum, whether reviewing the 1970 or the 1984 legislative history, it is clear that the CSA was intended as a solution to the problems of illicit drug use, drug trafficking,

and drug diversion. Congress never intended through the CSA to empower the Attorney General to rule upon the legitimacy of medical practice in the States.

II. The States, not the Attorney General acting through the Controlled Substances Act, regulate medicine.

The Attorney General's current interpretation of "legitimate medical purpose" and the "public interest" results in the direct regulation of medicine in the States and indeed the Attorney General argues for a national standard of care, *e.g.*, that "the 'standard of medical practice generally recognized and accepted' for purposes of the CSA, * * * is a national one." Pet. Br. 35, quoting *Moore*, *supra*, 423 U.S. 122, 139.

The Attorney General further argues that there is a trend away from the "locality rule" applicable in medical malpractice actions, Pet. Br. 36, and complains that if the CSA "incorporates the views of each of the 50 States * * *, [then] the *prosecution of physicians* would become much more difficult." Pet. Br. 35 (emphasis added).

The Attorney General commits several errors. First, with respect to prosecuting physicians, fifty different state malpractice standards should be of no consequence to the Attorney General because malpractice--or ordinary medical negligence--even when it involves controlled substances, is not a criminal act. See nn. 11-14, *supra*.

Second, the "locality rule" presents an *intra*state issue only. In those states that have dispensed with the locality rule, they have merely decided that the standard of care shall

be uniform throughout the state, in both rural and urban settings, meaning that the rural practitioner is no longer held to a lesser standard of care than is his or her big-city counterpart. Thus, to the extent that a state dispenses with the locality rule, it is a state-level decision only, it impacts civil malpractice actions only, and it has no impact on federal drug diversion prosecutions where the issue is whether a DEA-registered practitioner is diverting controlled substances out of the closed system, from legitimate to illicit channels.

Third, although some highly urban states have adopted a standard of care that speaks in "national" terms,[20] these

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[20] Rhode Island provides a good example of the rationale behind the adoption of a national standard of care:

> In sum, the traditional locality rules no longer fit the present-day medical malpractice case. * * *
>
> * * * the Legislature failed to employ any reference to the "similar locality" rule. We conclude that this omission was deliberate and constitutes a recognition of the national approach to the delivery of medical services, *especially in the urban centers of this country, of which Rhode Island is certainly one.*
>
> Accordingly we join the growing number of jurisdictions that have repudiated the "same or similar" communities test in favor of a national standard and hold that a physician is under a duty to use the degree of care and skill that is expected of a reasonably competent practitioner in the same class to which he or she belongs, acting in the same or similar circumstances.

Sheeley v. Memorial Hosp., 710 A.2d 161, 166-167 (R.I., 1998) (emphasis added).

states are in the minority.[21] More importantly, a state's decision to adopt a so-called national standard of care remains a state-level decision, requiring the exercise of state power; it does not mean that a state has surrendered its traditional role to regulate medicine, or to legislate exceptions to its "national" standard of care.

Fourth, and perhaps most importantly, Oregon has decided. When Oregon enacted, amended, and implemented its Death With Dignity Act, it established the standard of care regarding medical treatment near the end of life. Oregon also continues its tradition of a community standard of care, complete with a locality rule:

> **Duty of care;** * * * (1) A physician * * * licensed to practice medicine * * * by the Board of Medical Examiners for the State of Oregon has the duty to use that degree of care, skill and diligence that is used by ordinarily careful physicians * * * in the *same or similar circumstances in*

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[21] Contrary to the Attorney General's argument that a national standard of care predominates (Pet. Br. 36), more modern authority than that cited by the Attorney General reveals that more than 30 years later, less than half the states joined the trend that started in the 1970s. See, *e.g. Estate of Hagedorn ex rel. Hagedorn v. Peterson*, 690 N.W.2d 84, 89 (Iowa, 2004) (modified locality rule); *Jinkins v. Lee,* 807 N.E.2d 411, 421 (Ill., 2004) (locality rule); *LaFramboise v. Thompson* 329 F.Supp.2d 1054, 1056 (D.N.D., 2004) (locality rule); *see, also,* James O. Pearson, Jr., J.D., *Modern Status of "Locality Rule" in Malpractice Action Against Physician Who is Not a Specialist*, 99 A.L.R.3d 1133 (1980) (updated through 2004).

> *the community of the physician* * * *
> or a *similar community*.

Or. Rev. Stat. § 677.095 (emphasis added).

The Attorney General is no more empowered to reject the standard of care set out in the Oregon Death With Dignity Act than he is to reject Oregon's community standard of care, or its locality rule. These are state-level decisions, and it is the States, not the Federal Government, that regulate medicine. See, *e.g.*, *Linder v. United States*, 268 U.S. 5, 18 (1924) ("Obviously, direct control of medical practice in the States is beyond the power of the Federal Government"); *Liggett Co. v. Baldridge*, 278 U.S. 105, 112 (1928) (the States have authority to regulate drug prescriptions and pharmacists); *Semler v. Dental Examiners*, 294 U.S. 608, 611 (1934) (Oregon has authority to regulate the practice of dentistry within its borders); *United States v. Oregon Med. Soc.*, 343 U.S. 326, 338 (1951) (practice of medicine within Oregon is not interstate commerce); *Barsky v. Board of Regents*, 347 U.S. 442, 449 (1953) ("It is elemental that a state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there. It is a vital part of a state's police power"); *Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 387 (2002) (determination of medical necessity and standards of reasonable care are "quintessentially state-law" determinations). Although the Attorney General criticizes *Linder*, *supra*, as an outdated *Lochner*-era opinion (Pet. Br. 37, 40), similar propositions are found in *Barsky* and *Rush Prudential HMO*, *supra*.

This is no small point of dispute. The framers of the Constitution "split the atom of sovereignty" two ways:

horizontally among the three branches of government and vertically between the federal and state governments. See *Alden v. Maine*, 527 U.S. 706, 714-15, 751 (1999); *Printz v. United States*, 521 U.S. 898, 921-22 (1997). As this Court recently explained:

> This separation of the two spheres is one of the Constitution's structural protections of liberty. "Just as the separation and independence of the coordinate branches of the Federal Government serve to prevent the accumulation of excessive power in any one branch, *a healthy balance of power between the States and the Federal Government will reduce the risk of tyranny and abuse from either front.*"

Printz, 521 U.S. at 921 (emphasis added); quoting *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991).

The Congress, when legislating and later amending the CSA, was certainly aware of the traditional and constitutional allocation of power that resides at the core of our federal form of government, and it expressly provided that, "absent a positive conflict," the CSA does not prohibit the states from legislating on, "subject matter which would otherwise be within the authority of the State." See 21 U.S.C. § 903.[22]

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[22] Section 903 (Application of State law) provides:

(continued...)

Thus, the Attorney General may enforce the "uniform national policy" intended by Congress to prevent illicit drug use, drug trafficking, and drug diversion and, at the same time, Oregon practitioners acting in accord with state law, authorized by the Board of Medical Examiners and registered with the DEA, may possess, prescribe, and/or dispense schedule II substances within "the course of their professional practice," and in the "public interest." These two policies are not mutually exclusive, and there is no positive conflict between state and federal law such that the two "cannot consistently stand together." 21 U.S.C. § 903. In view of the plain language of the CSA, decades of jurisprudence, and the demonstrated intent of Congress, all discussed above, the Attorney General's contrary interpretation of the CSA and its implementing regulations seeks to accomplish too much. See *Raygor v. Regents of University of Minnesota,* 534 U.S. 533, 543 (2002) ("When Congress intends to alter the usual constitutional balance between the States and the Federal Government, it must make its intention to do so unmistakably clear in the language of the statute")(internal quotation marks omitted).

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[22](...continued)

> No provision of this subchapter shall be construed as indicating an intent on the part of the Congress *to occupy the field in which that provision operates*, including criminal penalties, to the exclusion of any State law on the same subject matter *which would otherwise be within the authority of the State*, unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together.

21 U.S.C. § 903 (emphasis added).

III. The power to regulate commerce between the States does not authorize federal usurpation of medical practice in the States, or the manner in which Oregonians die.

For the purposes of this discussion, the power of Congress to schedule or ban drugs, or to create a closed system or regulation, is not challenged. However, the Attorney General's expansive reinterpretation of 21 C.F.R. § 1306.04 (legitimate medical purpose) and 21 U.S.C. § 823(f) (public interest), does nothing to further those ends.

Congress, unlike the States, does not possess a general police power. *United States v. Lopez*, 514 U.S. 549, 566-67 (1995). Rather, "[e]very law enacted by Congress must be based on one or more of its powers enumerated in the Constitution." *United States v. Morrison*, 529 U.S. 598, 607 (2000). The commerce power is the power, "to prescribe the rule by which commerce is to be governed." *Lopez*, 514 U.S. at 553; quoting, *Gibbon v. Ogden,* 9 Wheat. 1, 196 (1824). Congress may not, "use a relatively trivial impact on commerce as an excuse for broad general regulation of state or private activities." *Lopez,* 514 U.S. at 558. Although statutes come to the courts bearing a presumption of constitutionality, *Morrison*, 529 U.S. at 607, any enactment that purports to be premised upon the commerce clause must in fact bear a substantial relationship to the regulation of interstate commerce. See, *e.g.*, *id.* at 613-19 (Congress lacked authority to establish tort remedy for violence based on gender); *Lopez,* 514 U.S. at 561-67 (Congress lacked authority to prohibit carrying a gun within 1000 feet of a school; impact upon interstate commerce was too attenuated).

Congressional enactments premised upon the power to regulate commerce are more carefully scrutinized when they invade areas of "traditional state concern." See, *e.g.*, *Lopez*, 514 U.S. at 564-68. Regulating the practice of medicine has long been regarded as a traditional state concern. See discussion and authorities, *supra*, 41-45. To uphold the Attorney General's enforcement directive is to go from regulating drug trafficking and diversion into regulating the practice of medicine within the states, a line that may not be crossed:

> The authority of the federal government may not be pushed to such an extreme as to destroy the distinction, which the commerce clause itself establishes, between commerce "among the several States" and the internal concerns of a State. That distinction * * * is vital to the maintenance of our federal system.

Labor Board v. Jones & Laughlin, 301 U.S. 1, 30 (1937).

Each Congressional enactment and subsequent interpretation must stand or fall on its own merits. The provision at issue in *Lopez* was section 1,702 of the Crime Control Act of 1990. This Court did not ask whether sections 1 through 1,701 were valid, or pertained to interstate commerce, but focused exclusively upon section 1,702. Here, the similarly narrow question is whether the Attorney General's expansive reinterpretation of a 1984 amendment (see 21 U.S.C. § 823(f)--"public interest") and an agency rule (see 21 C.F.R. § 1306.04--"legitimate medical purpose"), exceeds the Commerce Clause power.

The prescriptions in question are issued by state-licensed physicians, and filled by state-licensed pharmacists, in full compliance with the closed system of control established by the CSA. The prescriptions are to be used for what the State of Oregon has determined is within the course of professional practice. The medications are types commonly prescribed by physicians, and there are no allegations that these prescriptions have or will enter into the stream of illicit commerce. The Federal Government's legitimate interest in regulating interstate commerce has been fulfilled.

The concerns that led to this Court's decision in *Raich* do not apply here. Prescribing controlled substances to dying Oregonians for use as authorized by the State would not "leave a gaping hole" in the closed system of regulation, and prohibiting such use is not "necessary and proper" to prevent drug trafficking or drug diversion, which is the core purpose of the CSA, especially those provisions upon which the Attorney General relies. Indeed, the Attorney General does not, and cannot, point to a hole in the closed system that his new interpretation fills, nor can he explain how the purpose of the CSA would be undercut if this activity is not regulated.

Although the Constitution grants certain powers to Congress, the States have a constitutionally-protected role in the federal scheme as, "residuary sovereigns and joint participants in the governance of the Nation." *Alden*, *supra*, 527 U.S. at 748. The rights of the States are not confined to those expressly enumerated in the text of the Constitution, but also include other rights recognized at the time the Constitution was ratified or implicit in its design. Id. at 713-15, 728-32. "[I]t was neither necessary nor proper to define the powers retained by the States" because they retain all

powers they had before enactment of the Constitution, "except so far as they may be abridged by that instrument." *U.S. Term Limits, Inc. v. Thornton*, 514 U.S. 779, 801 (1995); quoting *Sturges v. Crowninshield*, 4 Wheat. 122, 193 (1819).

Just as judicial enforcement of "separation of powers" prevents one branch from usurping functions reserved for another branch, the courts similarly enforce the vertical separation of powers, to keep the Federal Government from usurping the powers and role reserved for the States. *Morrison*, 529 U.S. at 616-17, n.7. Here, the Attorney General's enforcement directive, specifically his expansive reinterpretation of 21 C.F.R. § 1306.04 (legitimate medical purpose) and 21 U.S.C. § 823(f) (public interest), is a direct attempt to regulate medical practice in the States, and it therefore exceeds not only the scope of the CSA, but also the limits of the Congressional power to regulate commerce.

CONCLUSION

FOR THE FOREGOING REASONS, this Court is urged to affirm the Ninth Circuit Court of Appeals.

Respectfully submitted,

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